Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

12844

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APR 20 1998

COMPLAINT/INJURY REPORT

1. COMPLAINT NUMBER: NSV-6563

2. DATE OF COMPLAINT (Month/Day/Year): 3-31-98

3. FORM OF COMPLAINT
(1) ☒ TELEPHONE
(2) ☐ LETTER
(3) ☐ VISIT

4. SOURCE OF COMPLAINT
(1) ☒ CONSUMER
(2) ☐ GOVERNMENT ☐ L ☐ S ☐ F
(3) ☐ TRADE SOURCE
(4) ☐ OTHER (Indicate in Remarks)

5. COMPLAINANT IDENTIFICATION
a. NAME AND ADDRESS (Include Zip Code): [redacted]
b. AREA CODE AND TELEPHONE NUMBER
HOME [redacted]
WORK ( )

6. COMPLAINT OR INJURY
a. DESCRIPTION OF COMPLAINT/INJURY: Dizziness & increased heart rate after consuming "body right" Fen-Chi Herbal Weight Control Supplement capsules (contains ephedra). Also complained urine drug screen done while being admitted to hospital was positive for opiates, which he feels may be from the "body right" herbal product. Complainant reported he had a history of high blood pressure & arrhythmia ~~app~~ starting approx 2 years ago, but has not taken any medication for this for approx 1 year.

b. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT?
(1) ☐ NO (2) ☒ YES (Explain in Remarks)

7. INJURY OR ILLNESS RESULTED
(1) ☐ NO
(2) ☒ YES
(If "yes" complete items a through d)

a. EIR (HFC-161) NOTIFIED
(1) ☐ NO
(2) ☒ YES
DATE 4-2-98

b. TYPE SYMPTOMS — ONSET (HR.)
1. ☐ VOMITING
2. ☐ NAUSEA
3. ☐ DIARRHEA
4. ☐ FEVER
5. ☐ SKIN/EYE IRR.
6. ☐ HEADACHE
7. ☒ OTHER See Remarks
Dizziness, tachycardia

c. ATTENDING HEALTH PROFESSIONAL
(1) ☐ NO (2) ☒ YES
(If "yes" give name, address, and phone number)
[redacted]

d. HOSPITALIZATION REQUIRED
(1) ☐ NO (2) ☒ YES
(If "yes" give name, address, phone number and dates)
[redacted]
4-20/23-98

8. PRODUCT AND LABELING
a. BRAND NAME: body right
b. PRODUCT NAME: Fen-Chi Herbal Weight Control Supplement
c. SIZE AND PACKAGE TYPE: 150 capsule plastic btl
d. NAME AND LOCATION OF STORE WHERE PURCHASED: [redacted]
e. PACKAGE CODE/SERIAL NUMBER/ETC.: 9107577 ink stamped on lb
EXP/USE BY DATE:
f. DATE PURCHASED: approx 4-5 wks ago
g. PRODUCT USED (If "yes" enter date) See Remarks
(1) ☐ NO (2) ☒ YES
h. AMT REMAINING: 46 capsules

9. MANUFACTURER/ DISTRIBUTOR OF PRODUCT
a. HOME DISTRICT: DEN
b. C.F. NO.: 1719247
c. NAME AND LOCATION OF FIRM (Include Zip Code)
Natures Sunshine Products Inc
Spanish Fork, UT 84660
d. IMPORT PRODUCT
(1) ☒ NO
(2) ☐ YES

10. EVALUATION AND DISPOSITION
a. PROBLEM KEYWORD
(1) CODE (2) DESCRIPTION
RX Tachycardia

b. EVALUATION
(1) ☐ NOT AN FDA OBLIGATION
(2) ☐ OBLIGATION, NO VIOLATION
(3) ☒ FDA ACTION INDICATED
(4) ☐ INSUFFICIENT INFORMATION UNABLE TO EVALUATE

c. DISPOSITION
(1) ☒ IMMEDIATE FOLLOW-UP
(2) ☐ F/U NEXT EI
(3) ☐ CLOSED WITHOUT FURTHER INVESTIGATION
(4) ☐ REFERRED TO OTHER FEDERAL AGENCY (Closes File)
(5) ☐ REFERRED TO STATE/LOCAL AGENCY (Closes file)
(6) ☐ REFERRED TO OTHER FDA ____ DISTRICT

11. PRODUCT CODE: 54FCE09

12. INFORMATION COPIES TO:
☐ HFB-100 ☐ HFZ-343
☐ HFD-730 ☐ HFC-161
☐ HFV-236 ☒ HFC-130
X HFS-635

REMARKS 6.b: Complainant wants copy of analysis of 98-651-955

7.b & 8.g: Symptoms appeared suddenly approximately 1 or 2 weeks after starting to take capsule from most recently purchased bottle, however complainant stated he had taken capsules from a previous bottle for approx 2 weeks earlier. He stated capsules were taken according to ~~label~~ label directions. Also stated his wife who had been taking the product for several weeks also experienced severe headaches & had trouble sleeping after starting to take capsules from this ~~most recently purchased btl. Wife has history of migraine headaches.~~

NAME AND TITLE: Donald E. Dodson, Investigator
DATE: 3-31-98

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FORM FDA 2516 (1/98)

*U.S. GPO: 1998-312-208/61737

P.03 FDA [redacted]

COMPLAINT / INJURY FOLLOW-UP

1. COMPLAINT NUMBER: NSV-6563

2. ACTION REQUESTED
(1) [X] INVESTIGATION
(2) [X] COLLECT SAMPLE
(3) [ ] INSPECTION
(4) [ ] OTHER

(a). REMARKS (Additional details)

(b) REQUESTING OFFICIAL'S NAME AND TITLE: M. Anthony Abel I, Supv CSO

(c) DATE REQUESTED: 3-31-98

(d) PRODUCT NAME: body right Fen-Chi Herb Weight Control Supplement Capsules

3. ASSIGNED TO: D.E.Dodson

(a) DUE BY:

4. ACTION TAKEN
(1) [X] INVESTIGATION
(2) [X] SAMPLE COLLECTED
(3) [ ] INSPECTION
(4) [ ] NONE

(a) SAMPLE NUMBER(s): 98-651-955

(b) DESCRIPTION OF ACTION TAKEN

Following phone receipt of preliminary information, complainant was requested to come in to CHT-RP where he was interviewed & remainder of capsules were obtained as part (Sub-1) of sample 98-651-955. Authorizations for Medical Records Disclosure were also signed by complainant, 2 of which are attached to this report. Complainants primary complaint was that upon admittance to hospital, a drug screen urinalysis was positive for opiates, which he denies using. During questioning about medications he had been taking, complainant informed me he had not taken anything for his heart problems for approximately 1 year, & stated he did not like to take medications. He said he had taken some aspirin or Tylenol for his back, but did not report to me it was Tylenol 3. Eventual review of hospital records however reported complainant had been taking Tylenol 3 which contains codeine & would therefore show up on a drug screen as an opiate. Complainant had a history of high blood pressure & arrhythmia and his symptoms following the use of the ephedra containing product were typical of reactions to such products, particularly to persons having such a history. He stated he had taken the body right ephedra containing herb product according to labeled directions (for weight loss). The product is labeled as containing 12.5mg per capsule ephedrine, & directions are for a total of 5 capsules per day. (See attached Continuation sheet)

(c) ACTION OFFICIAL (Typed) AND TITLE: Donald E. Dodson, Investigator

(d) ACTION DISTRICT: NSV

(e) DATE COMPLETED: 4-2-98

5. MANUFACTURER / DISTRIBUTOR / DEALER RESPONSIBLE

(a) HOME DIST.: DEN

(b). CF NO.: 1719247

(C) NAME AND ADDRESS: Natures Sunshine Products Inc
Spanish Fork, UT 84660

6. PROGRAM DATA

(a) OPERATION: 13

(b) PAC: 03R801

(c) PRODUCT CODE: 54FCE09

(d) EMP. HOME DIST.: L

(e) EMP. NO.: 110

(f) POS CL.: 2

(g) HOURS: 10

7. EVALUATION
(0) [ ] PENDING
(1) [ ] NO ACTION INDICATED (NAI)
(2) [ ] VOLUNTARY ACTION INDICATED (VAI)
(3) [ ] OFFICIAL ACTION INDICATED (OAI)
(4) [ ] NOT AN FDA OBLIGATION
(5) [X] REFERRED TO HOME DISTRICT
(6) [ ] INSUFFICIENT INFO. UNABLE TO EVAL.

8. FINAL DISPOSITION
(1) [ ] FOLLOW-UP NEXT E I
(2) [ ] WARNING LETTER
(3) [ ] CITATION
(4) [ ] SEIZURE
(5) [ ] INJUNCTION/PROSECUTION
(6) [ ] REFERRED TO OTHER AGENCY (Indicate Agency in Remarks)
(7) [ ] RECALL
(8) [ ] NO ACTION

9. INFO. COPIES TO
[ ] HFB-100
[ ] HFD-730
[ ] HFV-236
[ ] HFZ-343
[ ] HFC-161
[X] HFC-130
[X] HFS-635

REMARKS

NAME AND TITLE OF DISPOSITION OFFICIAL | DISPOSITION | DISPOSITION DATE

FORM FDA 2516a (1/90)

000002

1. COLLECTOR (Print or type name and signature)	2. DISTRICT	3. C/R NO.	4. DATE COLLECTED
Donald E. Dodson Donald E. Dodson	NSV	NSV-6563	4-2-98

5. REMARKS

An unopened bottle of the same lot # of the ephedra containing product was obtained from the same retail store from which Mr. [redacted] obtained the product, and was submitted as Sub-2 of 98-651-955.

Mr. [redacted] was taken to [redacted] emergency room on 3-20-98, was treated in the emergency room, admitted, and eventually discharged from the hospital on 3-23-98. Hospital records were reviewed on 4-1-98. There was no discharge summary in the records as this had not yet been dictated. His admission diagnosis was listed as Ventricular Tachycardia, Resolved. His age was listed as 47, & weight reported as 165-170 lb. Copies of selected portions of his hospital records are attached as follows:

Exhibit-1 History-Physical Examination
The second paragraph of this document states that a urine screen was positive for cocaine & opiates. Review of laboratory reports however do NOT report positive for cocaine, but do report positive for opiates & amphetamines (See Exhibit-4). Mr. [redacted] told me he had been questioned by the attending physician in the emergency room about use of drugs following the results of this drug screen, & denied any illicit drug use to both the ER physician & to me.

Exhibit-2 Physician Orders
Note that the first entry on this document lists one of the home medications that was being taken by Mr. [redacted] as Tylenol 3 (prn) which would likely show up on a drug urine screen as positive for opiates.

Exhibit-3 Emergency Room Records
The first page of these records also report the use of Tylenol 3 for back (pain).

Exhibit-4 Urinalysis Drug Screen
This urinalysis was performed on 3-20-98, the day of admission, & reports positive for amphetamines & opiates. As previously stated the positive for opiates would likely be from his use of Tylenol 3. Urine drug screens also often report positive for amphetamines when ephedrine has been taken, as from the ephedra containing herb product being used by Mr. [redacted]

1. COLLECTOR *(Print or type name and signature)*	2. DISTRICT	3. C/R NO.	4. DATE COLLECTED
Donald E. Dodson Donald E Dodson	NSV	NSV-6563	4-2-98

5. REMARKS

A phone call was made to Mr. [redacted] on 4-2-98 to ask him if he had in fact been taking Tylenol 3 prior to his hospital admission. Mr. [redacted] stated he occasionally takes Tylenol 3 when his back pain becomes severe, usually only about 1 per day. He said he does not remember for sure, however stated he may have taken some prior to his hospital admission.

The symptoms reported by Mr. [redacted] appear to be typical of adverse reactions occurring with use of ephedra containing products, particularly to persons having histories of heart problems.